REMARKS

Reconsideration of the allowability of the present application is requested respectfully.

Status of the Claims

Claims 1 to 5, 15 to 20, and 35 to 46 were acted upon by the Examiner in the Office Action dated April 26, 2004. Claims 35 and 41 have been amended. Claims 1 to 5 and 15 to 20 have been cancelled. No claims have been added. Accordingly, Claims 35 to 46 are presented for examination.

Support for Claim Amendments

Claims 35 and 41 have been re-written as independent claims. Accordingly, no new matter has been added.

ARGUMENTS

In response to the Examiner's Office Action dated April 26, 2004, Applicant respectfully traverses the Examiner's rejection of Claims 1 to 6, 15 to 20, and 35 to 46.

The §112, First Paragraph, Rejections of Claims 1 to 6 and 15 to 20

The Examiner has rejected Claims 1 to 6 and 15 to 20 under 35 U.S.C. §112, first paragraph, as containing new subject matter and for failing to demonstrate that at the time of filing applicant was in possession of the presently claimed invention. In particular, the Examiner asserts that the now recited microparticle size range (at least 50% of the microparticles are greater than 0.6 μm and at least 50% of the microparticles are less than 5 μm) is not contemplated in the instant specification. In the reply dated October 6, 2003, applicant has argued that the size limitation of "greater than 0.6 μm" is inherently present in claimed invention. In response, the Examiner has asserted that a structural limitation, such as a particle size or size range cannot be asserted to be inherently present. The Examiner has also suggested that applicant has admitted that "the specification/claims, as filed, 'set an upper limit (5 μM) to the median size of a microparticle population, but *failed to set a lower limit*'" (page 5 of the Office Action, dated April 26, 2004).

Applicant respectfully traverses the rejection.

Page 5 of the Office Action, dated April 26, 2004, states:

> While the functional property of a property of a product can be argued to be inherently present in a disclosed product, the structural limitations, such as, a particle size or size range cannot be asserted to be inherently present, especially after the explicit admission that the specification/claims, as filed, 'set an upper limit (5 μM) to the median size of a microparticle population, but *failed to set a lower limit*'.

In regard to the above passage, the quoted passage at the end is from applicant's reply dated September 17, 2002. Page 3 of this reply recites (emphasis added):

> The claims in the application as filed incompletely reflected this distinction. The claims set an upper limit (5 μM) to the median size of a

microparticle population, but failed to set a lower limit.

Thus, applicant has commented about the claims, but not the specification in the above quotation. Clearly, this passage refutes the Examiner's assertion that there has been an admission that "the specification/claims, as filed,...failed to set a lower limit". The importance of such a distinction is as follows. An admission that the specification and claims lack a lower limit supports the position that introduction of such a limitation into the claims would constitute the addition of new matter into the application. In contrast, an admission that the claims lack such a limitation, but not commenting on the specification, does not support an assertion that new matter has been claimed.

Referring to MPEP §604.08, an applicant may rely on the complete disclosure of the application (claims, specification, and drawings) when drafting and amending claims. Accordingly, it is irrelevant whether or not applicant has admitted that the originally filed claims lacked a limitation. What is critical is whether or not the specification supports such a limitation. As indicated in the reply dated October 6, 2003, the specification supports the assertion that microparticles of the present invention necessarily must be greater than 0.6 μm. In other words, microparticles inherently are greater than 0.6 μm.

The Examiner has not refuted applicant's assertion that one skilled in the art would recognize that microparticles of the present application inherently must be greater than 0.6 μm. Rather, the Examiner has asserted that "a structural limitation, such as a particle size or size range cannot be asserted to be inherently present". However, the Examiner provides no support for this assertion. If the Examiner intends to maintain this assertion, applicant respectfully requests the Examiner cite support for this assertion.

Furthermore, applicant respectfully traverses this assertion. The "Guidelines for Examination of Patent Applications under the 35 U.S.C. §112, ¶1, 'Written Description' Requirement" (66 Fed. Reg., Vol. 66, No. 4p, 1099-1111, 1105, col. 1 (Jan. 5, 2001); hereafter "the Written Description Guidelines") recites:

B. New or Amended Claims

The proscription against the introduction of new matter in a patent application serves to prevent an applicant from adding information that goes beyond the subject matter originally filed. Thus, the written description requirement prevents an applicant from claiming subject matter that was not adequately described in the specification as filed. New or amended claims which introduce elements or limitations which are not supported by the as-filed disclosure violate the written description requirement. While there is no *in haec verba* requirement, newly added claim limitations must be supported in the specification through express, implicit, or inherent disclosure.

There is nothing in the above passage that indicates that a structural limitation cannot be asserted to be inherently present. Indeed the above passage indicates that any newly added claim limitation can be supported by inherent disclosure.

Accordingly, applicant respectfully requests that the rejection of Claims 1 to 6 and 15 to 20 under 35 U.S.C. §112, first paragraph, be withdrawn.

The §112, First Paragraph, Rejections of Claims 35 to 46

The Examiner has rejected Claims 35, 36, 41, and 42 and those claims that depend thereon, that is, Claims 35 to 46, under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the invention at the time of filing.

Applicant respectfully traverses the rejection.

Claims 35 and 41 recite microparticles having a diameter range "from about 2.2 μm to about 4.3 μm". Dependent claims 36 and 42 recite microparticles having a diameter range from about 2.2 μm to less than 3.0 μm". The Examiner has asserted that the specification provides support for microparticles having an average diameter of 2.2 μm, but not the recited range.

Applicant submits that in addition to microparticles having an average diameter

of 2.2 μm (page 15, line 7, of application), the application discloses microparticles having an average diameter of 2.5 μm (page 15, Table 1, row 3), 3.0 μm (page 15, Table 1, row 4), 3.3 μm (page 15, Table 1, row 5), 2.4 μm (page 15, Table 1, row 6), 3.2 μm (page 15, Table 1, row 7), 3.0 μm (page 16, Table 2, row 3), and 4.3 μm (page 16, Table 2, row 4). Accordingly, the application discloses microparticles having an average diameter of 2.2, 2.4, 2.5, 3.0, 3.0, 3.2, 3.3, and 4.3 μm. In other words, applicant has disclosed eight data points with the 2.2-4.3 μm range. Since applicant has provided eight data points over a fairly small range (only 2.1 μm difference between 2.2 μm and 4.3 μm), applicant submits that one skilled in the art would recognize that the present disclosure indicates that applicant was in possession of this range.

Furthermore, in regard to Claims 36 and 42 which recite microparticles wherein "at least 50% of the microparticles are less than 3 μm", applicant respectfully directs the Examiner to page 5, lines 19 to 20, which recites "microparticles sized such that at least 50% of the microparticles are less than 5 μm, preferably less than 3 μm". Accordingly, there is explicit support in the specification for microparticles wherein "at least 50% of the microparticles are less than 3 μm".

Applicant also respectfully directs the Examiner to MPEP §2163.05(III), which states:

> With respect to changing numerical range limitations, the analysis must take into account which ranges one skilled in the art would consider inherently supported by the discussion in the original disclosure. In the decision in *In re Wertheim*, 541 F.2d 257, 191 USPQ 90 (CCPA 1976), the ranges described in the original specification included a range of "25%-60%" and specific examples of "36%" and "50%." A corresponding new claim limitation to "at least 35%" did not meet the description requirement because the phrase "at least" had no upper limit and caused the claim to read literally on embodiments outside the "25% to 60%" range, however a limitation to "between 35% and 60%" did meet the description requirement.

In the example cited in the MPEP, above, the specification disclosed the range "25%-60%" along with specific examples of "36%" and "50%." It was found that such a

disclosure ultimately supported a limitation of "between 35% and 60%". *I.e.*, the disclosure supported using a point that was about the same as the value of one of the specific examples, provided that this point was within the disclosed range. In the present case the specification explicitly discloses the range of less than 5 μm along with specific examples of 2.2, 2.4, 2.5, 3.0, 3.0, 3.2, 3.3, and 4.3 μm. Based on MPEP §2163.05(III), using a value about the same as any one of these data points as a lower limit would satisfy the description requirement.

Accordingly, applicant respectfully requests that the rejection of Claims 35 to 46 under 35 U.S.C. §112, first paragraph, be withdrawn.

The §102(b) Rejections of Claims 1 to 4, 6 and 15 to 18

The Examiner has rejected Claims 1 to 4, 6, and 15 to 18 under 35 U.S.C. §102(b) as being anticipated by Maloy et al. (Immunology 8: 661-667 (1994)).

Claims 1 to 4, 6, and 15 to 18 have been canceled. Accordingly, the rejection of Claims 1 to 4, 6, and 15 to 18 under 35 U.S.C. §102(b) as being anticipated by Maloy et al. have not been addressed.

The Examiner has further rejected Claims 1 to 4, 6, and 15 to 18 as being anticipated by Nixon et al. (Vaccine 14:1523-1530 (1996)) as evidence by Garcon et al. (U.S. Patent No. 6,372,227) and Rook et al. (U.S. Patent No. 6,056,964).

Claims 1 to 4, 6, and 15 to 18 have been canceled. Accordingly, the rejection of Claims 1 to 4, 6, and 15 to 18 under 35 U.S.C. §102(b) as being anticipated by Nixon et al. have not been addressed.

The §103(a) Rejections of Claims 5 and 19

The Examiner has rejected Claims 5 and 19, under 35 U.S.C. §103(a), as being

unpatentable over Nixon et al. in view of Cahill et al. (Vaccine 13: 455-462 (1995)) and Mills et al. (Infect. Immun. 61:399-410 (1993)).

Claims 5 and 19 have been canceled. Accordingly, the rejection of Claims 5 and 19 under 35 U.S.C. §103(a), as being unpatentable over Nixon et al. in view of Cahill et al. and Mills et al. have not been addressed.

The §103(a) Rejection of Claim 20

The Examiner has rejected Claim 20, under 35 U.S.C. §103(a), as being unpatentable over Nixon et al. in view of Jones et al. (J. Biotechnol. 44:29-36 (1996)).

Claim 20 has been canceled. Accordingly, the rejection of Claim 20 under 35 U.S.C. §103(a), as being unpatentable over Nixon et al. in view of Jones et al. has not been addressed.

Applicant respectfully requests that the Examiner contact the undersigned by telephone before issuing any further actions.

Respectfully submitted,

/J.M.D.

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